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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,411	02/07/2002	Glenn Barnes	MRI-021	1738

959 7590 07/01/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/01/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/071,411

Applicant(s)  
NAZARENKO et al.

Examiner  
Cynthia B Wilder

Art Unit  
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-36 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to an isolated nucleic acid and kit, classified in class 536, subclass 23.1.
  - II. Claims 12-26, drawn to a method for determining whether asthma patient is responsive to treatment, classified in class 514, subclass 44.
  - III. Claims 27-36, drawn to method for determining allelic variant, classified in class 435, subclass 6.

### ***Sequence election requirement applicable to all groups***

2. In addition, the Groups I-III reads on patentably distinct haplotypes selected from SEQ ID NOS: 4-6 and 7-8 and probes sequence selected from the group consisting of SEQ ID NOS: 9-60. Each sequence is patentably distinct because the sequences are chemically and structurally unrelated one to the other and a further restriction is applied to all groups. If the group I is elected, Applicant must elect one (1) haplotypes selected from SEQ ID NO: 4-6 and one (1) haplotype selected from SEQ ID NOS: 7-8 and an additional probe sequence selected from the group consisting of SEQ ID NOS: 9-60. If the group II or III is elected, Applicant must elect one (1) haplotypes selected from SEQ ID NO: 4-6 and one (1) haplotype selected from SEQ ID NOS: 7-8. (SEE MPEP 803.04).

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Applicant must identify the claims elected SEQ ID NO: corresponding to the elected claims to be prosecuted on the merit.

**Applicant is advised that examination will be restricted to only the elected 3 SEQ ID NOS: for Group 1 or the elected 2 SEQ ID NOS: for Groups II and III along with the corresponding claims and should not be construed as a species election.** Non-elected sequences in multiple sequence claims will be withdrawn from prosecution.

3. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~ I and II, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the probe and primers can be used in a materially different process such as in methods of nucleic acid cloning or purification or in methods of sequencing or in aptamer or antisense studies.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation leading to different effects. For example, Invention II is drawn to a method of determining whether a patient will be responsive to an inhibitor or drug by detecting the presence of an allelic variant in the patient's sample to determine the presence of a disorder and treating the patient with an appropriate drug to determine responsive whereas the

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invention III is drawn to a method detecting an allelic variant via hybridization with a probe complementary to the allelic variant site. The different invention are patentably distinct requiring different fields of search.

5. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for the other Group, restriction for examination purposes as indicated is proper

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

***Contact Information***


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw  
June 29, 2003

  
Cynthia B. Wilder, Ph.D.  
Patent Examiner  
Art Unit 1637